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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,365	01/05/2004	Willem Wesselink	P-10377.00	2235

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EXAMINER	
HELLER, TAMMIE K	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 06/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/751,365	WESSELINK ET AL.	
	Examiner	Art Unit	
	Tammie Heller	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22 and 33-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed on 10 April 2006 has been received and considered. Claim 15 has been amended and claims 1-22 and 33-41 are now pending in the application.

Specification

2. In view of the applicant's modification to the Specification, the Examiner is withdrawing the objection which was made against the specification in the last Office action.

Claim Objections

3. In view of the applicant's explanation of claim 10, the Examiner is withdrawing the objection which was made against claim 10 in the last Office action.

4. In view of the applicant's modification of claim 15, the Examiner is withdrawing the objection which was made against claim 15 in the last Office action.

Response to Arguments

5. Applicant's arguments with respect to claims 1-22 and 33-41 have been considered but are moot in view of the new ground(s) of rejection. The new grounds of rejection are based on the Examiner's inadvertent reference to U.S. Patent No. 5,534,016 to Boute rather than U.S. Patent No. 5,330,511 to Boute.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1, 2, 5-19, 22 and 33-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boute (U.S. Patent No. 5,330,511) in view of Park et al. (U.S. Patent No. 6,456,880). Regarding claims 1, 11, and 33-36, Boute discloses a dual chamber pacemaker which automatically optimizes the AV delay which includes test means to determine an optimal AV delay which corresponds to a pacing rate at a lower rate limit (LRL), rate means for setting a cardiac pacing rate at or near the LRL, AV delay means for varying an AV delay interval value, and QT means operative to measure variation of QT (see col. 4, ln. 7-17). However, Boute fails to disclose using a QT differential (QTD) and optimizing means which determines the optimal AV delay which corresponds to a minimal QTD. Park discloses an implantable cardiac stimulation device which measures a QTD to determine the optimal AV delay corresponding to a minimal QTD (see col. 9, ln. 36-40). This method of interval dispersion is utilized by Park in order to evaluate the relative changes in the interval dispersions over time and adjust the pacing parameters in response to said dispersions (see col. 2, ln. 43-45). Therefore, it would

have been obvious to one having ordinary skill in the art at the time of the invention to determine an optimal AV delay by measuring a QTD, the optimal AV delay corresponding to a minimal QTD, as taught by Park, in the AV delay optimization method of Boute in order to evaluate the relative changes in the QTD over time and adjust the pacing parameters in response to the QTD.

9. Regarding claim 2, Park teaches that QTD is determined by measuring QTmax and QTmin and determining the difference between QTmax and QTmin (see col. 9, ln. 36-40).

10. Regarding claim 5, Boute discloses AV delay means, including increment means for setting the AV delay values to a predetermined low value (AVmin) plus an integer (ΔAV) multiplied by a difference in time (Δt) and programming operating values of AVmin, ΔAV, and Δt (see col. 6, ln. 62-68 and col. 7, ln. 1-18).

11. Regarding claim 6, Boute discloses cycling through each of the AV values (see col. 6, ln. 62-68 and col. 7, ln. 1-18).

12. Regarding claim 7, Park discloses the step of evaluating the minimal value of QTD and changing the AV delay to the value corresponding to the minimal value if the minimal value different significantly from QTD of the AV value prior to initiating the test (see col. 9, ln. 48-52).

13. Regarding claim 8, Boute discloses storage means for storing test criteria and monitoring means for determining that said test criteria are met before initiating a test (see Claim 20).

14. Regarding claim 9, Boute discloses that the storage means stores criteria for a pacing mode and a QT stability value (see Claims 21 and 22).

15. Regarding claim 10, Boute discloses AV(r) means for generating an AV(r) curve based on the optimized AV delay (see block 72 in Figure 4B and AV(r) curve in Figure 2).

16. Regarding claim 12, the Examiner takes the position that the pacemaker of Boute is a programmable apparatus which carries out the modulation steps set out in claim 11.

17. Regarding claim 13, Boute discloses incrementally increasing and decreasing a test AV delay with respect to each of the base values (see col. 7, ln. 33-35).

18. Regarding claim 14, Boute discloses increasing AV delay in n predetermined discrete steps and decreasing AV delay in n predetermined discrete steps (see col. 7, ln. 33-35).

19. Regarding claim 15, Boute discloses storing the value of n and the value of the discrete steps, where n is at least 1 (see col. 7, ln. 33-35).

20. Regarding claim 16, Boute discloses changing the AV delay in small steps from 75 to 400 ms in steps of 25 ms, therefore, n equals at least 2 (see col. 3, ln. 47-50).

21. Regarding claim 17, Boute discloses that AV means comprises a set of m programmable values, AVmin, which are used as a basis for the optimal AV delay determination.

22. Regarding claim 18, Park discloses determining when the minimum dQT is different from a prior dQT, and that the AV delay is altered only when the optimized AV delay is different from the prior operating AV delay (see col. 9, ln. 48-52).

23. Regarding claim 19, Park discloses that the test is automatically repeated when it is found that the minimum dQT is not significantly different from a previous dQT (see col. 9, ln. 52-53).

24. Regarding claim 22, Boute discloses AV(r) means for generating an AV(r) curve based on the optimized AV delay (see block 72 in Figure 4B and AV(r) curve in Figure 2).

25. Regarding claim 37, Boute discloses in Figures 4B, 6A, and 7 different optimization tests to be performed. Therefore, it is inherent that the device of Boute stores a plurality of optimization tests and selects the optimization test to be performed.

26. Regarding claim 38, Boute discloses reprogramming the test following the performed test (see col. 4, ln. 19-23).

27. Regarding claim 39, Boute discloses setting a paced heart rate at which a test is performed (see block 54 in Figure 4B).

28. Regarding claim 40, Boute discloses setting the paced heart rate at about the device LRL (see block 54 in Figure 4B).

29. Regarding claim 41, because Boute discloses generating an AV(r) curve (see block 72 in Figure 4B and AV(r) curve in Figure 2), it is inherent that he sets the paced heart rate at a plurality of rate values.

30. Claims 3, 4, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boute in view of Park as applied to claims 1, 2, 5-22 and 33-41 above, and further in view of van der Veen et al. (U.S. Patent No. 5,713,930, cited by

applicant). Boute and Park disclose the invention essentially as claimed, but fail to disclose the steps of setting time t to a predetermined value less than 10 seconds or a predetermined number of discrete cardiac cycles. Van der Veen discloses a dual chamber pacing system and method which controls the AV interval, including digital controller/timer 330, which specifies what timing intervals are employed and controls the duration of the timing intervals (see col. 5, ln. 48-50). Van der Veen discloses that the timing interval may be one cardiac cycle or two seconds (see col. 5, ln. 62-64) in order to allow the microprocessor to analyze sensor data and update the AV interval. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to utilize the timing intervals taught by van der Veen in the invention of Boute and Park in order to allow the microprocessor ample time to analyze sensor data and update the AV interval.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tammie Heller whose telephone number is 571-272-1986. The examiner can normally be reached on Monday through Friday from 7am until 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766

TKH